

REMARKS

The Examiner's rejection of claims 3-11 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is respectfully traversed.

Applicant has amended claim 3 to make it clear as to what the oil phase components are dissolved in. In addition, the word "ceramides" has been corrected to the singular "ceramide".

In claim 10, the term "synthetic compounds" has been deleted.

Accordingly, the rejection of claims 3-11 under 35 USC 112, should now be withdrawn.

The rejection of claims 1-11 under 35 USC 103(a) as being unpatentable over Popp (US Patent Publication 2006/0029657) in combination with Foldvari (USP 5,853,755) is respectfully traversed.

The Examiner alleges that the method of preparation in Popp is the same as the method of preparation in the subject application and that therefore the presence of multilayered liposomes is implicit. We disagree with this allegation.

The disclosure in Popp et al is directed to a composition for skin protection. Popp does not describe a liposome being produced from the components thereof and no data exists in the description of Popp et al to identify the production of a liposome. Since Popp does not identify the production of a liposome, a method for preparing multilayered liposomes cannot be implicit. Moreover, since Popp does not teach the use of a fatty acid, it is not believed possible to produce multilayered liposomes in Popp as is taught and claimed in the subject application.

Foldvari '755 is directed to biphasic multimellar vesicles, which need not be multilayered, whereas the present invention is directed solely to a multilayered liposome for transdermal

absorption. The multilayered liposome of the present invention is formed without the use of a high-pressure homogenizer as is conventional in the formation of a liposome. Instead, the desired multilayered liposome for transdermal absorption was prepared in accordance with the present invention by selecting and mixing specific components in a specific particle size range without using a high-pressure homogenizer. More specifically, claim 1, as amended, requires the sizes of the particle to fall within the narrow range of 800 to 1000 nm.

The formation of a multilayered liposome could not be identified in Fig. 1 of Foldvari, and the existence of a multilayer liposome cannot be verified in Figs. 2 and 3. In contrast, Fig. 4 in the specification of the present invention shows the liposome of the present invention as having multi-layers, and the particles are in a size range limited to 800-1000 nm, see Table 2 of the present specification). Therefore, the liposome according to the present invention is able to entrap a larger amount of active ingredient and is more structurally stable than the multilamellar vesicle of Foldvari (see Examples 3 and 4). These effects of the multilayer liposome of the present invention are unexpected and superior in comparison to the vesicles taught in Foldvari.

For all of the above reasons, claim 1, as now amended, is clearly patentable over Popp '657 taken by itself or in combination with Foldvari '755.

Claim 3, as amended, also requires a narrow particle size range of between 800-1000 nm and requires dissolving aqueous-phase components at between 50-75°C with dissolved oil-phase components at the same temperature and then mixing and agitating the resulting mixture at a rate of 500-9000 revolutions per minute to form the multilayered liposomes. This methodology is not taught in Foldvari. Accordingly, claim 3 is also clearly patentable over Popp taken alone or in combination with Foldvari '755.

Claims 4, 6, 7 and 8 are dependent on claim 3 and are therefore believed patentable for the same reasons as given above. Claims 9, 10 and 11 are dependent upon claim 1 or claim 3 and are therefore believed patentable for the same reasons as given above.

Reconsideration and allowance of claims 1-11 is respectfully solicited.

Respectfully submitted,

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